PACKAGE LEAFLET: INFORMATION FOR THE USER

Levetiracetam Stragen
solution for infusion

Levetiracetam Stragen 5 mg/ml solution for infusion
Levetiracetam Stragen 10 mg/ml solution for infusion
Levetiracetam Stragen 15 mg/ml solution for infusion
Levetiracetam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT LEVETIRACETAM STRAGEN IS AND WHAT IT IS USED FOR

Levetiracetam Stragen is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).
Levetiracetam Stragen is used:
- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalization). Levetiracetam has been given to you by your doctor to reduce the numbers of fits.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalisation in adults, adolescents and children from 4 years of age
  - myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
  - primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalized epilepsy (the type of epilepsy that is thought to have a genetic cause).

Levetiracetam Stragen is an alternative for patients when administration of antiepileptic oral medicine is temporarily not feasible.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN LEVETIRACETAM STRAGEN

Do not use Levetiracetam Stragen
- if you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are given Levetiracetam Stragen
- if you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- if you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as Levetiracetam Stragen have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy
  Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose.
  In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and loss of skills you may notice that the seizures remain present or are becoming worse during your treatment.
  If you experience any of these new symptoms while taking Levetiracetam Stragen, see a doctor as soon as possible.

Children and adolescents
Levetiracetam Stragen is not indicated in children and adolescents below 16 years on it's own (monotherapy).
Other medicines and Levetiracetam Stragen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are taking this medicine.
Levetiracetam can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor.
You should not stop your treatment without discussing this with your doctor.
A risk of birth defects for your unborn child cannot be completely excluded.
Breast-feeding is not recommended during treatment.
Driving and using machines
Levetiracetam Stragen may impair your ability to drive or operate any tools or machinery, as Levetiracetam Stragen may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.
Levetiracetam Stragen contains sodium
Levetiracetam Stragen 5 mg/ml contains 3.50 mg of sodium (main component of cooking/table salt) per ml.
This is equivalent to 17.5% of the recommended maximum daily dietary intake of sodium for an adult.
Levetiracetam Stragen 10 mg/ml contains 3.23 mg of sodium (main component of cooking/table salt) per ml.
This is equivalent to 16.15% of the recommended maximum daily dietary intake of sodium for an adult
Levetiracetam Stragen 15 mg/ml contains 2.40 mg of sodium (main component of cooking/table salt) per ml.
This is equivalent to 12% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW LEVETIRACETAM STRAGEN IS GIVEN

A doctor or a nurse will administer Levetiracetam Stragen as an intravenous infusion.
Levetiracetam Stragen must be administered twice a day, once in the morning and once in the evening, at about the same time each day.
The intravenous formulation is an alternative to your oral administration. You can switch from the film-coated tablets or from the oral solution to the intravenous formulation or reverse directly without dose adaptation. Your total daily dose and frequency of administration remain identical.
Adjunctive therapy and Monotherapy (from 16 years of age).
Adults (≥ 18 years) and adolescents (12-17 years) weighing 50 kg or more:
Recommended dose: between 1000 mg and 3000 mg each day.
When you will first start taking Levetiracetam Stragen, your doctor will prescribe you a **lower dose** during 2 weeks before giving you the lowest daily dose.
Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:
Recommended dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.
Method and route of administration:
Levetiracetam Stragen is for intravenous use. The solution for infusion should be administered over 15-minutes.
Duration of treatment:
There is no experience with administration of intravenous levetiracetam for a longer period than 4 days.
If you stop using Levetiracetam Stragen
If stopping treatment, as with other antiepileptic medicines, Levetiracetam Stragen should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam Stragen treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam Stragen.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them.
Tell your doctor immediately, or go to your nearest emergency department, if you experience:
- Weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction;
- Swelling of the face, lips, tongue and throat (Quincke's oedema);
- Flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes and the involvement of other body organs (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]);
- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function;
- A skin rash which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*);
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*);
- A more severe form of rash causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*);
- Signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy.

The most frequently reported adverse reactions were nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.
Very common: may affect more than 1 in 10 people
- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 people
- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon: may affect up to 1 in 100 people
- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect up to 1 in 1,000 people
- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- delirium;
- encephalopathy (see sub-section "Tell you doctor immediately" for detailed description of symptoms);
- seizures may become worse or happen more often
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram)
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function;
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*);
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients;
- limp or difficulty walking.
- combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, low level of consciousness (may be signs of a disorder called neuroleptic malignant syndrome). Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

Very rare: may affect up to 1 in 10,000 people
- repeated unwanted thoughts or sensations or the urge to do something over and over again (Obsessive Compulsive Disorder).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEVETIRACETAM STRAGEN

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the overwrap, bag and carton after EXP:.
The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
This medicinal product is for single use only, any unused solution should be discarded.
Medicinal product with particulate matter or discoloration should not be used.
Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Levetiracetam Stragen contains
The active substance is levetiracetam.
- Each ml contains 5 mg of levetiracetam.
  Each 100 ml bag contains 500 mg of levetiracetam.
- Each ml contains 10 mg of levetiracetam.
  Each 100 ml bag contains 1000 mg of levetiracetam.
- Each ml contains 15 mg of levetiracetam.
  Each 100 ml bag contains 1500 mg of levetiracetam.

The other ingredients are: sodium acetate trihydrate, glacial acetic acid, sodium chloride, water for injections.
What Levetiracetam Stragen looks like and contents of the pack
Levetiracetam Stragen is a clear, colourless to light yellow solution for infusion that is available in a single-use, ready-to-use 100 ml dual port bag with an aluminum over wrap.
It is available in three different concentrations in cartons of 10 bags
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Marketing Authorisation Holder
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stragen

12771/12772/12773_A01

CLIENT:	**STRAGEN**
PRODUCT:	**LEVETIRACETAM STRAGEN (Levetiracetam)**
JOB:	**LEAFLET**
COUNTRY:	**UK**
RRC:	**12771/12772/12773**
VERSION:	**A01**
DATE:	**04.02.2025**
FORMAT:	**210 x 500 mm**
FONT:	**Univers Condensed 8 pts** **Eq. Times New Roman 9 pts**
PRINT:	**Black**

Levetiracetam Stragen (Levetiracetam)- LEAFLET - UK

DATE	RRC_VERSION N°	REASON FOR CHANGE
04.02.2025	12771/12772/12773_A01	Text update
03.02.2025	12771/12772/12773_A00	Text update
24.04.2024	12362/12363/12364_A00	Name: Levetiracetam Stragen + RRC
02.11.2022	10652/10653/10654/ 11179/11180/11181_A02	New RRC
23.06.2022	10652/10653/10654_A01	Text update
20.06.2022	10652/10653/10654_A00	Text update + new RRC
07.12.2020	09414/09415/09416_A05	Text update
07.12.2020	09414/09415/09416_A04	Text update
07.12.2020	09414/09415/09416_A03	Text update
05.10.2020	09414/09415/09416_A02	Text update
02.10.2020	09414/09415/09416_A01	Design update
01.10.2020	09414/09415/09416_A00	Text update + new RRC
23.10.2019	08645/08646/08651_A01	Text update
22.10.2019	08645/08646/08651_A00	Text update + new RRC
16.04.2019	07410/07411/07412_A01	Text update
15.04.2019	07410/07411/07412_A00	Text and logo update, new RRC
13.12.2016	06258/06260/06262_A05	Text update
13.12.2016	06258/06260/06262_A04	Text update + new RRC
24.11.2016	06269/06259/06261_A03	See Word “131-pl-uk-tc”
23.11.2016	06269/06259/06261_A02	See pdf “Kevesy_LEAFLET_UK_06269_06259_06261_A01_161118_corrections of a few typo...”
18.11.2016	06269/06259/06261_A01	See pdf “Kevesy_LEAFLET_UK_06269_06259_06261_A00_161118_with comments.pdf”
18.11.2016	06269/06259/06261_A00	See Word “131-pl-uk-tc”